

**REMARKS****Status of the Application and Claims**

With entry of this amendment, Applicants request reconsideration and allowance of pending claims 1-16 and 18-21. Claims 1-21 are stated as rejected. Applicants have amended claims 1-16 and 18-21. The limitation of “wherein qualitative or quantitative determination of the drug is achieved within at least 5 minutes but less than 30 minutes of the first part contacting the second part” added to claim 1 is supported by the Examples of the specification and, therefore, does not add new matter.

In addition, Applicants have added new claims 22 and 23, which are derived from the subject matter of the Examples and, therefore, do not add new matter.

Applicant acknowledges that the Office has withdrawn previous rejections to claims 1-3, 5-10, 12 and 14-21, claim 4, and claims 11 and 13 under 35 U.S.C. § 103(a), “in view of applicants’ amendments and arguments.” Office Action, 04/08/2004 at 2, ¶ 2.

**Rejection Under 35 U.S.C. § 112, Second Paragraph**

The Office rejected claims 1-16 and 18-21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter the applicants regards as its invention. *Id.* at 4, ¶ 5.

As amended, claim 1 refers to “gold material or latex particles” and so obviates the Office’s assertion that the claim is unclear. In addition, claims 2, 6, 8, and 12, as amended, recite the term “or” in describing the alternative limitations provided. Applicants respectfully note that this limitation is present in the other claims rejected by the Office, claims 10, 15, and 21, and so the alternative limitations in these claims have been represented properly. Accordingly,

Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The Office rejected claims 1-3, 5-7, 9-10, 12, 14-16 and 18-21 under 35 U.S.C. § 103(a) as being “unpatentable over Jehanli et al., (1996) and Baker et al., in view of Cole et al., (U.S. Patent 4,589,612).” *Id* at 5, ¶ 7.

As amended, claim 1, and therefore claims 2-10, 12, 14-16, 19-21, and new claims 22 and 23 include a limitation wherein “the qualitative or quantitative determination of the drug is achieved within at least 5 minutes but less than 30 minutes of the first part contacting the second part.” This limitation is not disclosed in Jehanli, Baker, or Cole. As the Office indicated, in Jehanli, “[c]olor development was terminated after 30 minutes. . . .” *Id.* at 7. Because there is no suggestion or motivation to produce a kit that produces a qualitative or quantitative determination in less than 30 minutes, the claimed invention is not obvious. Likewise, and to the extent the Office argues that Baker et al. and Cole et al. are adaptations of the “medical kit for qualitative or quantitative determination of a drug in a biological fluid” as allegedly taught by Jehanli et al., the claimed invention is not made obvious for at least same reason as above. Accordingly, Applicants request that the rejection be withdrawn.

Claim 4 is rejected under 35 U.S.C. § 103(a) as being “unpatentable over Jehanli et al., (1996) and Cole et al., (U.S. Patent 4,589,612) as applied to claim 1 above, and further in view of de Jaeger et al.” *Id* at 14, ¶ 9. For the same reasons stated above with respect to Jehanli et al. and Cole et al., the Applicants request that this rejection be withdrawn.

Claims 11 and 13 are rejected under 35 U.S.C. § 103(a) as being “unpatentable over Jehanli et al., (1996) and Cole et al., (U.S. Patent 4,589,612) as applied to claims 1, 10 and 12 above, and further in view of Esser.” *Id* at 16, ¶ 10. Applicants have canceled claims 11 and 13 with this Amendment. Accordingly, this rejection is moot.

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: October 8, 2004

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